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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/801,540	03/08/2001	Adrian Bot	A30571-A-PCT/USA-A	7183

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EXAMINER

WOITACH, JOSEPH T

ART UNIT	PAPER NUMBER
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1632

8

DATE MAILED: 10/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/801,540

File
Applicant(s)

BOT ET AL.

Examiner

Joseph T. Voitach

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 March 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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DETAILED ACTION

This application filed March 8, 2001 is a continuation-in-part of application 09/308,511 filed May 19, 1999, which is a 371 national stage filing of PCT/US97/21687, filed November 21, 1997, which claims priority to application 08/755,034, filed November 22, 1996, now patent 6,204,250.

Applicants preliminary amendment filed March 8, 2001, has been received and entered. The specification has been amended. Claims 1-3 are pending and currently under examination.

Specification

The nucleotide sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825. Applicant's attention is directed to the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998). Specifically, the specification contains sequences identified by sequence identifier numbers, however neither a CFR nor a sequence listing has been filed.

Appropriate correction is required.

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The absence of proper sequence listing did not preclude the examination on the merits however, **for a complete response to this office action, applicant must submit the required material for sequence compliance.**

In addition it is noted that the following order or arrangement is preferred in framing the specification and, except for the reference to the drawings, each of the lettered items should appear in upper case, without underling or bold type, as section headings. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) Title of the Invention.
- (b) Cross-Reference to Related Applications.
- (c) Statement Regarding Federally Sponsored Research or Development.

The disclosure is objected to because of the following informalities: the priority information must be present in the first line of the specification, however this information in the specification as amended is preceded by other information.

Appropriate correction is required.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686

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F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-19 of U.S. Patent No. 6,204,250. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of instant application and U.S. Patent No. 6,204,250 are both drawn to a method of immunizing and infant against a target antigen. In particular, the claims of '250 provide methods wherein the target antigen is a viral antigen. In light of the teachings in the specifications and the method steps recited in the claims, the instant claims would be anticipated by the patented claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 1 and 2 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, claims 1 and 2 are incomplete because the method recites a method for immunizing, however the final step results only in the epitope being expressed. Amending the claim to recite --wherein the infant is immunized-- would obviate the basis of this rejection. Dependent claims are included in this rejection because they fail to clarify the basis of the rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Bot *et al.*

Claims 1-3 are drawn to a method of immunizing a mammalian infant to a target antigen, by expressing one or more relevant epitopes. Bot *et al.* teach the immunization of infant mice comprising the administration of recombinant nucleic acid encoding the NP peptide, and

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demonstrated a decrease viral titer in an infant mouse following challenge with influenza virus (see entire article). Bot *et al.* teach both the nucleic acid product and the method of use for immunizing. Thus, the claimed invention is anticipated.

Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Lai *et al.*.

Claims 1-3 are summarized above. Lai *et al.* teach that administration of the DNA results in immunization and protection against Hepatitis B infection (entire reference, summarized in abstract). Lai *et al.* teach both the nucleic acid product and the method of use for immunizing. Thus, the claimed invention is anticipated.

Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Assateerawatt *et al.* (1993).

Claims 1-3 are summarized above. Assateerawatt *et al.* teach that administration of the DNA results in immunization and protection against Hepatitis B infection in neonates (entire reference, summarized in abstract). Assateerawatt *et al.* demonstrate that greater than 90% of the neonates tested had increased protection to infection of Hepatitis infection. Assateerawatt *et al.* teach both the nucleic acid product and the method of use for immunizing. Thus, the claimed invention is anticipated.

Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by del Canho *et al.*

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Claims 1-3 are summarized above. del Canho *et al.* teach that administration of the DNA results in immunization and protection against Hepatitis B infection (entire reference, summarized in abstract). It was found that the vaccine is highly immunogenic in infants when vaccinated at 0, 1 and 6 months of age with the recombinant vector encoding a Hepatitis B antigen. del Canho *et al.* teach both the nucleic acid product and the method of use for immunizing. Thus, the claimed invention is anticipated.

Conclusion


No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (703)305-3732.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (703)305-4051.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (703) 308-2141.

Joseph T. Woitach


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